

**Opening State for the Honorable Gregg Harper
Chairman, Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
“The State of U.S. Public Health Biopreparedness: Responding to Biological
Attacks, Pandemics, and Emerging Disease Outbreaks”
June 15, 2018**

(As prepared for delivery)

Good morning, today the Subcommittee continues its long-standing oversight of the U.S. public health system's preparedness to respond to biological threats and emerging infectious diseases that endanger the public health. The purpose of today's hearing is to hear from top public health experts on the good work being done at their agencies to protect the public, and to explore where improvements in biopreparedness may still be needed.

The biological threats facing the United States in today's global society are varied, ever-evolving, and in some cases, intensifying. The CDC just reported that the seasonal influenza claimed the lives of 172 children during the most recent flu season, making it the deadliest seasonal flu season for children on record. In recent years the U.S. has also seen an increase in the number of antibiotic resistant bacteria.

Around the world, viruses are emerging, adapting, and in some cases, re-emerging. Currently, there is an Ebola outbreak in West Africa and a Nipah virus outbreak in India, that has killed at least 17 people.

In recent years, we have also seen humans in China contract the H7N9 strain of influenza, which had been confined to birds. The H7N9 influenza strain is rated by the CDC's Influenza Risk Assessment Tool as posing the greatest risk to cause a possible pandemic.

The 2013 ricin mailings addressed to President Obama and Senator Roger Wicker that originated in my home state of Mississippi, as well as the 2001 anthrax mailings and foreign terrorist threats, is a reminder of the risk of intentional biological attacks.

Today's hearing is especially timely given that the Committee is considering bipartisan legislation, sponsored by Ms. Brooks and Ms. Eshoo, to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA), which is set to expire at the end of September. Passage of PAHPA's reauthorization would not only provide critical certainty for public

health agencies and industry partners, it would also bring about some much-needed reforms.

One such reform, proposed in the legislation, is transferring control of the Strategic National Stockpile from the CDC to HHS' Office of the Assistant Secretary for Preparedness and Response to improve management of the Stockpile.

A year ago, HHS's Office of Inspector General reported systemic issues with security and inventory management of the Stockpile, risking CDC's ability to deploy the stockpile during a public health emergency. These issues need to be addressed, as does improving the training of state and local stakeholders on deployment of medical countermeasures.

Administrative reforms are also of interest. For example, are there ways to improve the timeliness of the decision-making process on threat assessments and appropriate countermeasures?

Effective threat detection has been a subject of Committee oversight. In 2016, the Committee questioned the CDC about the effectiveness of its Laboratory Response Network (LRN), or LRN, which is responsible for developing assays for public health labs to test for the presence of federal select agents. In a May 2017 letter to the Committee, the CDC reported that the LRN had only developed three assays approved by FDA to detect specific federal select agents. While the LRN has also had assays cleared by the FDA under Emergency Use Authorization, after nearly 20 years of this program with about \$135 million in funding over the last decade, could the LRN have cleared a significantly higher number of assays through the more rigorous FDA 510(k) process?

Finally, maintaining public confidence in critical federal biopreparedness research is essential. In response to safety lapses in 2014 and to an expert panel's recommendations, the CDC and FDA each formed new offices in 2015 to centralize and elevate oversight of laboratory safety, with the directors of those offices reporting directly to the agency head. These changes sent a strong message that lab safety was a top priority backed by the clout of direct backing from the agency head. Unfortunately, both agencies seem to be backtracking from this good direction, in the FDA's case less than a year after this Administration approved the direct-report reorganization. The sudden change is curious, and would seem to be a step in the wrong direction. We need to hear more details about the basis for this new direction.

I would like to thank the distinguished members of our panel for being here today and for your service to our country. I now recognize the Ranking Member of the Subcommittee from Colorado, Ms. DeGette, for five minutes.